K011213

MAY 16 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

1.0 Submitted By:

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2.0 Date Submitted

April 11, 2001

3.0 Device Name(s):

3.1 Proprietary Names

SYNCHRON LX®20 PRO System

3.2 Classification Names

Discrete photometric chemistry analyzer for clinical use [862.2160]

4.0 Legally Marketed Device

The SYNCHRON LX®20 PRO System claims substantial equivalence to the SYNCHRON LX®20 System currently in commercial distribution.
FDA 510(k) Number K965240

5.0 Device Description

The SYNCHRON LX20 Systems are fully automated, computer controlled, clinical chemistry analyzers intended for the *in vitro* determination of a variety of general chemistries, therapeutic drugs, and other chemistries of clinical interest in biological fluids such as serum, plasma, urine, and cerebral spinal fluid (sample type is chemistry dependant). The analyzers operate in conjunction with reagents, calibrators, and controls designed for use with the system. The instruments feature bar code identification of samples and reagents. They automatically dilute samples and deliver them to the reaction cuvette along with reagents and reaction constituents. The systems analyze up to 41 analytes per sample. Major hardware components include a reagent compartment, sample and reagent cranes, cartridge chemistry section, modular chemistry section, sample carousel and crane, hydropneumatics, electronics, and power supplies.

In addition to the same version 2.0 software upgrade, the LX20 PRO System incorporates the use of the following additional features:

1. LPIA (Large Particle Immunoassay) Module

The LPIA module is a detection system for large particle immunoassays. Latex particles (300 – 500 nm diameter) are used in the reagents to enhance the signal of antibody binding reactions. The detector measures at 940 nm.

The LPIA module consists of two printed circuit boards and a detector packaged into a box. The LPIA module fits onto an LX20 system to the left of the standard photometer near the sample carousel. Fiber optic cable connections allow the module to interact with the system software. A reference LED is used to provide feedback to the measuring detector.

2. TS-CTS (Thick Stopper-Closed Tube Sampling) Module

The Thick-Stopper Closed Tube Sampling (TS-CTS) module has been optimized for Becton Dickinson VACUTAINER® Tubes with HEMOGARD™ Closure sample collection tubes. TS-CTS enables through the cap sampling on thick-stoppered collection tubes.

The TS-CTS key components include the cap piercer assembly, blade assembly, sample wheel and lifter assembly and associated brackets, covers and alignment tool.

3. Flat Panel LCD touch-screen monitor

6.0 Intended Use

The SYNCHRON LX20 PRO Systems are fully automated, computer controlled, clinical chemistry analyzers intended for the *in vitro* determination of a variety of general chemistries, therapeutic drugs, and other chemistries of clinical interest in biological fluids such as serum, plasma, urine, and cerebral spinal fluid (sample type is chemistry dependant).

7.0 Comparison to the Predicate (Description of the Modification to the Legally Marketed Device)

The SYNCHRON LX20 system has been upgraded to an LX20 PRO system through the following hardware upgrades: Closed Tube Sample (TS-CTS) module, LPIA (Large Particle Immunoassay) detector module. There is also a name change to LX 20 PRO.

8.0 Summary of Performance Data

Performance data from validation testing supports equivalency.

Section 1: ADMINISTRATIVE INFORMATION

1.0 Submitted By:

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2.0 Sponsor Address/FDA Registration Number

Beckman Coulter, Inc.
200 S. Kraemer Blvd. W-104
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Establishment Registration No. 2050012

3.0 Product Name/Classification Name and Number

Proprietary Names

SYNCHRON LX®20 PRO System

Classification Names

Discrete photometric chemistry analyzer for clinical use [862.2160]

4.0 Device Classification

FDA has classified clinical chemistry test systems of this type into Class I

5.0 Section 514 Compliance

This Special 510(k): Device Modification submission is prepared pursuant to the FDA publication: The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications – Issue Date: March 20, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 6 2001

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Re: 510(k) Number: K011213
Trade/Device Name: Synchron LX®20 Pro System
Regulation Number: 862.1665, 862.1030, 863.1035, 862.1050, 862.1065, 862.1070, 862.1100, 862.1110, 862.1145, 862.1160, 862.1170, 862.1175, 862.1215, 862.1225, 862.1345, 862.1360, 862.1410, 862.1415, 862.1440, 862.1465, 862.1475, 862.1495, 862.1580, 862.1600, 862.1635, 862.1700, 862.1705, 862.1770, 862.1775, 862.2320, 862.2540, 862.3030, 862.3040, 862.3100, 862.3150, 862.3170, 862.3240, 862.3250, 862.3320, 862.3350, 862.3450, 862.3620 862.3630, 862.3645, 862.3650

Regulatory Class: II

Product Code: JGS, LDP, DMT, CJE, CKA, JIF, DKZ, JFJ, GTQ, CIT, DIS, JXM, KLT, CHH, DIH, CGS, JHW, DIO, KXT, JFM, LCD, JQB, JJJ, LCP, JJO, JIY, CFJ, CHI, CJW, MSJ, CDQ, JFL, CGX, CGA, CZP, DEW, DFT, CEM, CGZ, JFP, CEO, CEK, DDG, JGJ, DJR, KXS, DCF, DJG, LCM, DLZ, DIP, JZJ, JXN, DHR, DKJ, LDJ, KLS, KLI, LCR, CIG, JMO, CDT, KLI, JHB, LEG

Dated: April 19, 2001
Received: April 20, 2001

Dear Ms. Hellie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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510(k) Number (if known): K011213

Device Name: **SYNCHRON LX®20 PRO System**

Indications for Use:

The SYNCHRON LX20 PRO Systems are fully automated, computer controlled, clinical chemistry analyzers intended for the *in vitro* determination of a variety of general chemistries, therapeutic drugs, and other chemistries of clinical interest in biological fluids such as serum, plasma, urine, and cerebral spinal fluid (sample type is chemistry dependent).

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011213

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (per 21 CFR 801.109) OR Over-the-Counter Use _____ Optional Format 1-2-96